



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

NOVARTIS INSTITUTES FOR
BIOMEDICAL RESEARCH, INC.
220 MASSACHUSETTS AVENUE
CAMBRIDGE MA 02139

COPY MAILED

DEC 23 2009

OFFICE OF PETITIONS

In re Patent No. 7,582,782 :
Baeschlin, et al. :
Application No. 10/579,427 : ON APPLICATION FOR
Issued: September 1, 2009 : PATENT TERM ADJUSTMENT
Filed: May 12, 2006 :
Atty Docket No. 33522-US-PCT :

This is in response to the PETITION REGARDING PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d), filed October 21, 2009. Patentees request that the determination of patent term adjustment be corrected from four hundred sixty-five (465) days to five hundred seventy-seven (577) days.

The request for reconsideration of patent term adjustment is **DISMISSED** with respect to making any change in the patent term adjustment determination under 35 U.S.C. § 154(b) of 465 days

On September 1, 2009, the above-identified application matured into U.S. Patent No. 7,582,782 with a revised patent term adjustment of 465 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d). The 465-day patent term adjustment includes a period of adjustment of 98 days pursuant to 37 CFR 1.702(b) for the Office taking in excess of three years to issue the patent. Patentees dispute the calculation of this 465-day period.

Patentees argue that the period of adjustment for Office failure to issue the patent within three years is 112 days, not 98 days. In addition, patentees assert that pursuant to the courts interpretation of the overlap provision as set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), that a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day."

Patentees contend that since the days calculated under 37 C.F.R. § 1.703(a)(1) (483 days) and 37 C.F.R. § 1.703(b) (112 days) do not occur on the same day that they do not overlap and therefore, the correct days charged against the USPTO under § 1.702(a)(1) and § 1.702(b) is five hundred ninety-five (595) days. (Thus, given the applicant delay of 18 days, patentees contend that the patent should have issued with a revised patent term adjustment of 577 (595 - 18) days.

The Office does not concur with patentees' calculation of the over three-year period or patentees' definition of overlap.

First of all, the over three-year period is 98 days, not 112 days. This application was pending three years and 98 days (not 112 days) after the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, May 26, 2006. In asserting a period of delay of 112 days, patentees fail to consider that this application is a national stage application¹.

Accordingly, the period of adjustment under § 1.702(b) for over three year pendency is 98 days, counting the number of days beginning on May 27, 2009 and ending on September 1, 2009, the date the patent issued.

Secondly, the Office does not agree with patentees' interpretation of the overlap provision. It is the Office's position that the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the application filing date overlap with the actual dates in the periods accorded for Office delay during the pendency of the application. The relevant overlap provision, 35 U.S.C. 154(b)(2)(A), limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

¹Patentees are informed that the Three Year Delay period is triggered by the application's commencement date, not the § 371 fulfillment date. Patentees incorrectly calculate this as a 112 day period based on the application having fulfilled requirements under 35 U.S.C. § 371 on May 12, 2006, and the patent issuing on September 1, 2009.

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was

pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the commencement date, May 26, 2006, and ending on the date of issuance of the patent, September 1, 2009 (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1), 483 days of patent term adjustment were accorded during the pendency of the application for Office delay. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), 98 days of patent term adjustment accrued for Office issuance of the patent more than 3 years after the filing date of the application.

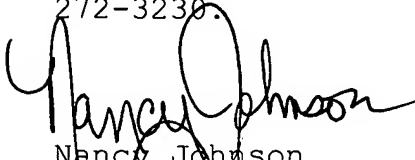
The 98 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 483 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 98 days and the 483 days is neither permitted nor warranted. 483 days is the actual number of days issuance of the patent was delayed.

Accordingly, at issuance, the Office properly entered 0 additional days of adjustment pursuant to § 1.702(b) for a total of the greater period of 483 days for Office delay.

In view thereof, no change will be made in the patent term adjustment of 465 days (483 days of Office delay - 18 days of applicant delay).

Pursuant to patentees' authorization, the \$200.00 fee set forth in 37 CFR 1.18(e) will be charged to deposit account no. 50-4409. No additional fees are required.

Telephone inquiries specific to this decision should be directed to Senior Petitions Attorney Shirene Willis Brantley at (571) 272-3230.

A handwritten signature in black ink, appearing to read "Nancy Johnson". The signature is stylized with a large, looped initial "N" and a cursive "Johnson".

Nancy Johnson
Senior Petitions Attorney
Office of Petitions